

THE ROCKEFELLER UNIVERSITY

1230 YORK AVENUE , NEW YORK, NEW YORK , 10021-6399

January 27, 2003

Select Agent Program Centers for Disease Control and Prevention 1600 Clifton Road, N.E. Mail Stop E-79 Atlanta, GA 30333

Dear Sirs:

I am writing in response to the Centers for Disease Control and Prevention's solicitation for comments on 42 CFR Part 73, Interim Final Rule, Possession, Use, and Transfer of Select Agents and Toxins published in the Federal Register, Vol. 67, No. 240, on Friday, December 13, 2002.

The Rockefeller University supports the comments and recommendations for 42 CFR Part 73 submitted by the Howard Hughes Medical Institute (HHMI) on January 21, 2003. I have attached a copy of the HHMI "Comments on 42 CFR Part 73" for your reference. Specifically, the basis for the University's support and endorsement is that the recommendations will ensure the appropriate availability of biological agents and toxins for research, education, and other legitimate purposes and will make the safeguard and security requirements for persons possessing, using, or transferring a listed agent or toxin risk-based. These provisions are requirements of the "Public Health Security and Bioterrorism Preparedness and Response Act of 2002." Generally, the adoption of the recommendations of the HHMI will allow for an effective performance-based security plan, lessen the administrative burden of the Final Rule, and ensure the relevance of the Final Rule to the biomedical research environment.

In addition to the comments and recommendations submitted by HHMI, I also recommend that the proposed section on Records (§73.15) be revised to parallel the USDA's Interim Final Rule recordkeeping sections (7 CFR 331.14 and 9 CFR 121.15) as published in the Federal Register, Vol. 67, No. 240, on December 13, 2002. The proposed USDA requirements for records are more performance-based — an approach that has proven successful in the academic and research setting. Having the same recordkeeping requirements in both the CDC and USDA rules will also help ensure consistency in records for programs that involve overlapping agents.

We appreciate the opportunity to comment on the Interim Final Rule.

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Sincerely.

Amy Wilkerson
Associate Vice President

Research Support

Enclosure: Comments on 42 CFR Part 73, Interim Final Rule

Possession, Use and Transfer of Select Agents and Toxins